DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Olympus Optical Co., LTD
% Ms. Laura Storms-Tyler
Director, Regulatory Affairs and Quality Assurance
Olympus America, Inc.
Two Corporate Center Drive
Melville, NY 11747-3157

JUL 27 2015

Re: K011149
Trade/Device Name: DISPOSABLE BENDING CANNULA PR-233Q
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODD, FGE
Dated (Date on orig SE ltr): March 19, 2001
Received (Date on orig SE ltr): April 16, 2001

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent letter of May 15, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number(if known): Not assigned yet · K011149

Device Name: DISPOSABLE BENDING CANNULA PR-233Q

Indications for Use:

This instrument has been designed to be used with an Olympus endoscope to inject contrast medium in the biliary and pancreatic ducts, although it is not designed for the deep insertion into the pancreatic duct.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optoinal Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011149

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SMDA 510(k) SUMMARY

DISPOSABLE BENDING CANNULA PR-233Q

A. Submitter's Name, Address, Phone and Fax Numbers

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjuku Monolis Nishi-Shinjuku, Shinjuku-ku Tokyo, Tokyo 163-0914 Japan
Registration No.:	8010047
Address, Phone and Fax Numbers: Of R&D Division, Endoscope Group	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 81- 426-42-2891 FAX 81-426-46-5613

B. Name of Contact Person

Name: Address, Phone and Fax Numbers:	Laura Storms-Tyler Olympus America Inc. Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5688 FAX: (631) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Trade Name:	Disposable Bending Cannula PR-233Q
Common Name:	Disposable Cannula
Classification:	21 CFR 876.1500 Endoscope and accessories 21 CFR 876.5010 Biliary catheter and accessories
Predicate Device:	PR-23Q DISPOSABLE BALL TIP CANNULA K950729 KD-6G WIRE GUIDED PAPILLOTOMY KNIVES K950166

D. Description of the Device(s)

The subject device is a cannula which has a bending function (angle wire), to be used in accordance with Intended Use of the Device. This bending function enables the subject device to be manipulated in 2 directions and leads to easier insertion into the biliary and pancreatic ducts.

E. Intended Use of the Device(s)

The subject device, DISPOSABLE BENDING CANNULA PR-233Q has been designed to be used with an Olympus endoscope to inject contrast medium in the biliary and pancreatic ducts, although it is not designed for the deep insertion into the pancreatic duct.

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, this subject device Disposable bending cannula PR-233Q does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness.